REMARKS

Claims 1-7, 9-16, 18-21 are pending in the present application, with 1, 9, and 15 being the independent claims. Claims 1-7, 9-16 and 18-21 currently stand rejected.

Applicants would like to thank the Examiner for conducting the telephonic interview held on August 3, 2007. The contents of the interview are discussed in the relevant sections below.

Specification

The examiner states that the title of the application is not descriptive. Applicants have amended the title to more clearly indicate the subject matter of the application. At the August 3 interview the Examiner indicated acceptance of the new title.

Claim Objections

Claims 5 and 10 are objected to because it recites: "an medical need." Applicants have amended the claims accordingly, and at the August 3 interview the Examiner indicated that the amendment would correct the informality.

Claim Rejections - 35 USC § 101

Claims 15, 16 and 18-21 stand rejected under 35 U.S.C. 101 as non-statutory because the claims are directed to software per se. Claims 1-7, 9, 10, 15, 16 and 18-21 are further rejected under 35 U.S.C. 101 because the claimed subject matter lacks a practical application and fails to produce a practical, concrete, and tangible result. Applicants have amended the claims to more clearly recite their application to the *selection* of medical products. Furthermore, the Examiner stated during the August 3 interview that the software per se rejection can be overcome if claim 14 was amended to further recite a processor executing instructions. Applicants have amended claim 15 accordingly.

In light of the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility," the applicants respectfully submit that by "specifically reciting in the claim the practical application" (see Interim Guidelines, page 21 line 6), claims 1-7, 9, 10,

15, 16, and 18-21 produce a useful, tangible and concrete result. In particular, referring to pages 19-22 of the Interim Guidelines, the claim now recites a result that is:

(1) "useful" because the result is specific, substantial and credible, i.e., a computer implemented method for selecting a medical product for development based upon information collected by users,

(2) "tangible" because the invention produces a real-world result – enables, for example, a medical product developer to select a product for development to address a need that is not addressed by available products, and

(3) "concrete" because the result is substantially repeatable (i.e., the method selects a product for development when submissions match a predetermined number, thus yielding substantially repeatable results given similar information).

Thus, applicants respectfully submit that claims 1-7, 9, 10, 15, 16 and 18-21 are allowable as reciting statutory subject matter. Applicants respectfully request that the examiner withdraw the rejection.

Claim Rejections - 35 USC §112

Claims 1, 6, 15, and 20 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the examiner maintains that various claimed limitations are not described in the specification.

Applicants respectfully direct the examiner to the application and the following table describing the corresponding claim elements.

Claim Element	**Application Text**
selecting the submission indicative of the medical need	A validation committee may review and analyze the data and provides feedback to R&D to address the problem. (0026)
for development of a medical product	the identified unmet needs can then be sent to the product design teams to address the identified needs (0007)
where the submitted medical need matches a predetermined number of other submissions	Here, a predetermined level 802 is set. Unmet need is the only unmet need that has exceeded the predetermined level. (0034)

having the same primary topic	by periodically summarizing the data by the number of submissions in a particular category (0034)

During the August 3 interview the Examiner indicated that he would reconsider the rejection based upon Applicant's response. Applicants respectfully request that the examiner withdraw the rejection.

Claims 3, 5 and 7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to clearly state the items being referenced. The claims have been amended to address the rejection. Applicants respectfully request that the examiner withdraw the rejection.

Claim Rejections - 35 USC § 103

Claims 1-7, 9, 15, 16, and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over "MedWatch: The FDA Medical Products Reporting Program" and US 6,219,674 ("Classen"). The examiner contends that "accepting on said web site a submission indicative of a medical need not addressed by available medical products relating to the medical products from a plurality of users" is indicated on Page 9 of the MedWatch reference. Applicants respectfully disagree.

As explained during the August 3 interview, Page 9 of MedWatch states "Report Serious Adverse Events and Product Problems with All Medical Products to MedWatch." Thus MedWatch is designed to collect information about adverse events and problems associated with *existing products*. Claim 1 (as amended), on the other hand, recites "accepting on said web site a plurality of submissions indicative of medical needs *not addressed by available medical products*" (emphasis added) and is directed to, for example, the collection of information indicating the need for a product or service that may not currently exist. To further highlight the distinction, Applicants have amended the claim to recite "development of a *new* medical product" (emphasis added).

The examiner further contends that Classen discloses the step of "selecting the submission indicative of the medical need not addressed by available medical products for development of a medical product related to the selected medical need not addressed by

available medical products where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic." Applicants respectfully disagree.

The Examiner cites the Classen abstract and Col. 7 lines 10-12, which both describe a method for using product data to enhance the safety of an *existing* medical product. The examiner also cites Classen Col. 9 lines 10-34, which describes a method of analyzing the adverse events through the setting of thresholds to determine safe and commercially viable use of an *existing* product. Thus the threshold is set to indicate a problem with an existing product that may require corrective action. As explained during the August 3 interview, the cited passages do not disclose the analysis of submissions to select a submission indicating "a medical product related to the selected medical need *not addressed by available medical products*" (emphasis added) for "development of a *new* medical product" (emphasis added) as recited by the claim.

Accordingly, applicants submit that for at least the aforementioned reasons, all of the limitations of claim 1 are not taught or suggested by MedWatch alone or in combination with Classen. During the August 3 interview the examiner stated that the claims may be further placed in condition for allowance if they were amended to more clearly recite "a plurality of submissions" and to include the step of analyzing the plurality of submissions. Applicants have amended the claims accordingly. The Examiner indicated that he would reconsider the rejection based upon Applicant's response. Applicants respectfully request that the examiner withdraw the rejection. Claims 9 and 15 recite similar limitations to claim 1, and claims 2-7, 16, and 18-20 depend from claim 1, 9, and 15 and are thus believed allowable for at least the same reasons as described above with respect to claim 1.

CONCLUSION

Reconsideration of the outstanding rejections to the claims is respectfully requested in view of the above remarks. If the Examiner has any further suggestions to expedite the prosecution of the presently pending claims, please do not hesitate to contact the undersigned.

Date: August 7, 2007

/David M. Platz/
David M. Platz
Registration No. 60,013

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439